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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,526	10/11/2005	Toshikazu Kamiya	00005.001278.	4344

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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	PAPER NUMBER
1655	
MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,526	KAMIYA ET AL.	
	Examiner	Art Unit	
	MELENIE MCCORMICK	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,18-22 and 28-31* is/are pending in the application.

4a) Of the above claim(s) *3,18-22 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4-11 and 28-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I, claims 1-11 and 28-30 in the reply filed on 13 June 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicants also elected the species *Hydrangea macrophylla*, glucosamine and chondroitin sulfate.

Claims 3 and 9 are directed to a non-elected species and is withdrawn from consideration.

Claims 1-11, 18-22 and 28-31 are pending.

Claims 3, 9, 18-22 and 31 are withdrawn.

Claims 1-2, 4-11 and 28-30 are presented for examination on the merits.

Claim Objections

Claim 1 is objected to because of the following informalities: 'a' should be added following 'comprises' in line 1. Appropriate correction is required.

Claims 4-5 and 8-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. It is noted that although claims 4-5 and 8-9 are improper multiply dependent claims and would typically not be considered on their merits, in the effort to advance prosecution in this case, the Examiner has fully examined these claims on the merits.

Applicant is asked however, to correct the improper dependencies of these claims upon the next correspondence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 recite composition comprising a 'plant belonging to the genus *Hydrangea* or an extract of the plant and amino sugar or a salt thereof and/or glycosaminoglycan or a salt thereof'. It is not clear which ingredients the claim is referring to. Are all of these ingredient present in the claims or only some ingredients. If only some ingredients are present, which ones are present? Therefore, the claim is ambiguous and thus indefinite.

Claims 7-8 recite the limitation "or the additive for food and drinks" in line 1. There is insufficient antecedent basis for this limitation in the claim because all of the claims depend from claim 6, either directly or indirectly and claim 6 does not recite an additive for foods and drinks. Because claim 6 does not recite an additive, it is not clear if the composition of claims 7 and 8 is an additive for a food or not.

Claim 7 recites 'wherein it is used for prevention or treatment of arthritis.' (emphasis added) The word 'it' in this statement causes confusion because there are multiple embodiments in claim 6 and the Examiner cannot determine which embodiment 'it' is refering to. Subsequently, the ordinary artisan would have trouble trying to ascertain if they were infringing upon the claimed invention and therefore the claim is indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-11 and 28-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a treating agent for arthritis which comprises an aqueous ethanolic extract of Hydrangea macrophylla and amino sugar or a salt thereof and/or glycosaminoglycan or a salt thereof as active ingredients does not reasonably provide enablement for an agent for prevention of arthritis which comprises any plant belonging to the genus Hygrangea, including Hydrangea macrophylla or any extract of any plant of the genus Hydrangea, including Hydrangea macrophylla and amino sugar or a salt thereof and/or glycosaminoglycan or a salt thereof as active ingredients. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a preventing or treating agent for arthritis which comprises a plant belonging to the genus Hygrangea, or an extract of the plant and amino sugar or a salt thereof and/or glycosaminoglycan or a salt thereof as active ingredients.

Applicants have reasonably described/disclosed that a composition comprising an aqueous ethanolic extract of Hydrangea macrophylla, amino sugar or a salt thereof and/or glycosaminoglycan or a salt thereof as active ingredients for treating arthritis. However, the claims (see e.g. claim 1) encompass using the claimed composition comprising any plant belonging to the genus Hygrangea, or any extract of a plant belonging to the genus Hydrangea macrophylla, amino sugar or a salt thereof and/or glycosaminoglycan or a salt thereof as active ingredients for preventing arthritis. As evidenced by wikipedia.org, there are 70-75 species in the genus Hydrangea. Applicants have not demonstrated a representative number of species of hydrangea which would be effective for treating or preventing arthritis. Applicants have only demonstrated an aqueous ethanolic extract of Hydrangea macrophylla is effective for treating arthritis (see e.g. pages 37 and 40). Because it is not expected that all 70-75 species would have the same effect, Applicants are not enabled for the broad scope of the claims. In addition, because different solvent extracts would contain different active ingredients, it would not be expected that all types of extract would have the same therapeutic effect.

Applicants have also not demonstrated that the instantly claimed composition is effective in preventing arthritis. The term “prevention” is understood in the art to

encompass total protection from disease or injury. Thus, given the high level of required effect, a high level of evidence showing prevention is also required. The instant specification, however, fails to teach that the administration of the instantly claimed composition is able to prevent arthritis.

Applicants have reasonably demonstrated that a composition comprising an aqueous ethanolic extract of Hydrangea macrophylla, glucosamine and chondroitin sulfate is effective in suppressing arthritis (see e.g. pages 37 and 40 of the instant specification). Applicants have not, however, demonstrated that the administration of any plant belonging to the genus Hygrangea, or any extract of any plant belonging to the genus Hydrangea macrophylla, amino sugar or a salt thereof and/or glycosaminoglycan or a salt thereof as active ingredients is effective for preventing arthritis.

As referenced by Vikas Garg, M.D. (Arthritis Basics), the cause of most forms of arthritis is unknown (see e.g. page 7). Garg further provides risk factors that may increase the likelihood of developing arthritis, however, Garg also cautions that not everyone with the disease may exhibit risk factors and not everyone with risk factors will exhibit the disease (see e.g. page 7). Thus, it is clear that there is unpredictability with regard to arthritis. Garg also teaches that there is no certain way to prevent arthritis (see e.g. page 4, last paragraph). The state of the art is unpredictable concerning agents for treating arthritis. In addition, the state of the art of herbal medicine is unpredictable. As evidenced by Shaw et al., herbal remedies can have unpredictable adverse effects (see abstract).

Therefore, in view of the breadth of the claims encompassing a composition which comprises any plant from the genus Hydrangea or any extract of any plant of the genus Hydrangea for treating or preventing arthritis, the lack of sufficient guidance or data or evidence supporting an arthritis preventative effect of the claimed composition, and the unpredictability in the art of treatment of arthritis, as evidenced by Garg, one of skill in the art would find that undue experimentation would be required to practice the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-11 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorgente et al. (US 6,162,787) in view of Guardia et al. (2001) in view of Balado and further in view of Matsuda et al. (1999).

Sorgente et al. beneficially teach that oral administration of a composition comprising glucosamine or its salts and chondroitin sulfate (a type of glycosaminoglycan, as evidenced by applicant' claim 5) and/or its salts is effective for treating arthritis (see e.g. claims 1 and 29). Sorgente et al. further teaches that the arthritis may be osteoarthritis or rheumatoid arthritis (see e.g. claims 21-22). Sorgente et al. also teaches that the composition may contain auxiliary compounds, such as

binders, vitamins, amino acids, fillers, gelatin, etc (see e.g. col 5, lines 51-57). Sorgente also discloses that the composition may be formulated as a tablet, capsule, suspension, aerosol spray and the like. A powder could be added to a food (i.e. a food additive) and a suspension reads on a drink.

Sorgente et al. does not explicitly teach that the composition additionally contains Hydrangea macrophylla or an extract thereof.

Guardia et al. beneficially teach that in an experimental model for inflammation, which is a suitable and simple model for evaluating potential anti-arthritic agents was used to determine the anti-inflammatory activity of flavonoids in adjuvant arthritis (see e.g. page 685-Discussion). Guardia et al. further teach that rutin was extremely effective in reducing inflammation (see e.g. page 685-Discussion). Guardia et al. further teach that the role of dietary flavonoids in the treatment of inflammatory diseases, such as rheumatoid arthritis is promising (see e.g. page 687).

Balado beneficially teaches that rutin was extracted and identified from the blossoms of *Hydrangea macrophylla* (see e.g. abstract).

Matsuda et al. beneficially teach that chemical constituents with anti-histamine activity were extracted from the leaves of *Hydrangea macrophylla* Seringe var. thunbergii Makino (see e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition for use in treating arthritis comprising an extract of *Hydrangea macrophylla*, glucosamine and chondroitin sulfate. A person of ordinary skill in the art would have had a reasonable expectation of success

in doing so based upon teaching of Sorgente et al. that a composition comprising glucosamine or its salts and chondroitin sulfate and/or its salts is effective for treating arthritis (see e.g. claims 1 and 29). In addition, based upon the teaching of Balado that rutin is extracted from *Hydrangea macrophylla* and the teaching of Guardia et al. that rutin is extremely effective in reducing inflammation in a rat arthritis model and shows promise for treating arthritis, a person of ordinary skill in the art would have been motivated to extract *Hydrangea macrophylla* for the rutin contained therein and add this extract to other known anti-arthritic agents, such as glucosamine and chondroitin sulfate as taught by Sorgente et al. "The idea for combining them flows logically from their having been used individually in the prior art"; *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). This rejection is based upon the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, See *In re Sussman*, 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943). A person of ordinary skill in the art would have had a reasonable expectation of success in particularly using the variety *Hydrangea macrophylla* Seringe var. thunbergii Makino because this was a known variety at the time and was known to contain therapeutic chemical constituents. Therefore, since *Hydrangea macrophylla* Seringe var. thunbergii Makino is simply a variety of *Hydrangea macrophylla,* one of ordinary skill in the art would reasonably expect this variety, which is known to chemical constituents in

the leaves, to contain rutin in the flowers, as disclosed by Balado. As previously stated, Sorgente et al. also disclose that the composition may be formulated as a tablet, capsule, suspension, aerosol spray and the like. A powder could be added to a food (i.e. a food additive) and a suspension reads on a drink. It would have therefore been obvious to one of ordinary skill in the art to formulate a composition comprising glucosamine, chondroitin sulfate and an extract *Hydrangea macrophylla* Seringe var. thunbergii Makino in these forms.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELENIE MCCORMICK whose telephone number is (571)272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655

/Patricia Leith/
Primary Examiner, Art Unit 1655